

Appendix F



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/093,151	07/24/2018	10029111	BTC.103PTXD1	6885

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
 (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

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I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office on the date shown below:

AMENDMENT UNDER 37 CFR §1.114
Patent Application
Docket No. BTC.103PTXD1

December 27, 2017

David Saliwanchik

David R. Saliwanchik, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	John P. Lacyk
Art Unit	:	3735
Applicant	:	Yi Jin
Serial No.	:	15/093,151
Conf. No.	:	6885
Filed	:	April 7, 2016
For	:	rTMS at Harmonics of Biological Signals

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 CFR §1.114

Sir:

A three-month Extension of Time, through and including December 27, 2017 is being authorized with the electronic filing of this paper.

A Request for Continued Examination (RCE) accompanies this paper.

In response to the Office Action dated June 27, 2017, please amend the above-referenced application as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this paper.

Remarks/Arguments follow the amendment section of this paper.

In the Claims

This listing of claims will replace all prior versions and listings of claims in this application.

1 (currently amended). A method of improving a physiological condition or a neuropsychiatric condition of a mammal which comprises subjecting the mammal to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric, wherein the mammal is a human.

2 (previously presented). The method of claim 1 wherein the non-EEG biological metric is heart rate, respiratory rate, or gastrointestinal movement rate.

3 (previously presented). The method of claim 1 wherein the rTMS frequency is equal to, or a harmonic or sub-harmonic of, a non-EEG biological metric that is closest to an intrinsic frequency in a desired EEG band.

4 (previously presented). The method of claim 3 wherein the non-EEG biological metric is heart rate.

5 (previously presented). The method of claim 1 wherein the physiological condition is concentration, sleep, alertness, memory, blood pressure, stress, libido, speech, motor function, physical performance, cognitive function, intelligence, height or weight.

6 (previously presented). The method of claim 1 wherein the neuropsychiatric condition is Autism Spectrum Disorder (ASD), Alzheimer's disease, ADHD, schizophrenia, anxiety, depression, coma, Parkinson's disease, substance abuse, bipolar disorder, a sleep disorder, an eating disorder, tinnitus, traumatic brain injury, post-traumatic stress syndrome, chronic pain, or fibromyalgia.

7 (previously presented). The method of claim 3 wherein the intrinsic frequency is in the delta band (<4 Hz), the theta band (4-8 Hz), the alpha band (8-13Hz), the beta band (13-30 Hz), the gamma band (25-100 Hz), or the Mu band (8-13 Hz).

8 (currently amended). A method of improving the symptoms of a ~~person~~ human having autism spectrum disorder (ASD) that comprises subjecting the person to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric.

9 (previously presented). The method of claim 8 wherein the non-EEG biological metric is the person's heart rate.

10 (currently amended). A method of improving the symptoms of a ~~person~~ human having Alzheimer's disease that comprises subjecting the person to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric.

11 (previously presented). The method of claim 10 wherein the non-EEG biological metric is the person's heart rate.

12 (currently amended). A method of improving the symptoms of a ~~person~~ human having chronic pain that comprises subjecting the person to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric.

13 (previously presented). The method of claim 12 wherein the non-EEG biological metric is the person's heart rate.

14 (new). The method of claim 1, wherein the rTMS frequency is equal to, or a harmonic or sub-harmonic of, a non-EEG biological metric having a highest coherence coefficient to an intrinsic frequency in a desired EEG band.

15 (new). The method of claim 8, wherein the rTMS frequency is equal to, or a harmonic or sub-harmonic of, a non-EEG biological metric having a highest coherence coefficient to an intrinsic frequency in a desired EEG band.

16 (new). The method of claim 10, wherein the rTMS frequency is equal to, or a harmonic or sub-harmonic of, a non-EEG biological metric having a highest coherence coefficient to an intrinsic frequency in a desired EEG band.

17 (new). The method of claim 12, wherein the rTMS frequency is equal to, or a harmonic or sub-harmonic of, a non-EEG biological metric having a highest coherence coefficient to an intrinsic frequency in a desired EEG band.

Remarks

Claims 1-13 were previously pending in the subject application. By this Amendment, claims 1, 8, 10, and 12 have been amended and new claims 14-17 have been added. Support for the claim amendments can be found throughout the subject specification and claims as originally filed. No new matter has been added by these amendments. Accordingly, claims 1-17 are now presented for consideration by the Examiner.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be construed as an indication of the Applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the amendments and remarks set forth herein, is earnestly solicited.

Claims 1-13 have been rejected under 35 U.S.C. §101 on the ground of statutory double patenting as claiming the same invention as that of claims 1-11 of prior U.S. Patent No. 9,308,385 (Your Ref: BTC-301US; Our Ref: BTC.103PTX). The Applicant respectfully traverses this rejection to the extent that it might be applied to the claims now presented for examination.

Though the Applicant does not necessarily agree that these claims as previously presented are subject to rejection under statutory double patenting grounds, in an effort to expedite prosecution, claims, 1, 8, 10, and 12 have been amended to recite that the methods are directed only towards humans.

A rejection based on statutory double patenting is appropriate only when an application claims identical subject matter to the claims of another application or issued patent. The test for whether an "identical" invention is being claimed is whether the claim in the present application can be infringed without *literally infringing* corresponding claims in the conflicting patent, and vice versa. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) (emphasis added).

The claims of the '385 patent could be infringed without *literally infringing* the claims of the present application. For example, the '385 patent claims are directed towards "modulating the brain activity of a mammal," whereas the present claims are directed towards improving the symptoms or conditions of a human. Thus, for example, application of the claimed methods to a dog would

infringe the claims of the ‘385 patent but would not literally infringe the claims in the present application.

The Applicant continues to note that if a double patenting rejection were appropriate at all, the analysis should be based on the doctrine of non-statutory double patenting. Non-statutory double patenting prohibits claims in a second patent that are “obvious” variations on claims in an earlier patent, i.e., claims that are not patentably distinct from the earlier claims. See MPEP § 804.

Finally, in order to provide further distinction to the claimed invention, new dependent claims 14-17 have been added to recite that the rTMS frequency is equal to, or a harmonic or sub-harmonic of, a non-EEG biological metric having a highest coherence coefficient to an intrinsic frequency in a desired EEG band.

Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §101.

In view of the foregoing remarks and the amendments above, the Applicants believe that the currently pending claims are in condition for allowance and respectfully request such action.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The Applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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DRS/kev/iam

Attachment: Request for Continued Examination (RCE)

I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office on the date shown below:

AMENDMENT UNDER 37 CFR §1.111
Patent Application
Docket No. BTC.103PTXD1

March 20, 2017
Linda Audette
Linda Audette, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : John P. Lacyk
Art Unit : 3735
Applicant : Yi Jin
Serial No. : 15/093,151
Conf. No. : 6885
Filed : April 7, 2016
For : rTMS at Harmonics of Biological Signals

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 CFR §1.111

Sir:

A two month Extension of Time, through and including March 21, 2017, is being authorized with the electronic filing of this paper.

In response to the Office Action dated October 21, 2016, please amend the above-referenced application as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this paper.

Remarks/Arguments follow the amendment section of this paper.

In the Claims

This listing of claims will replace all prior versions and listings of claims in this application.

1 (previously presented). A method of improving a physiological condition or a neuropsychiatric condition of a mammal which comprises subjecting the mammal to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric.

2 (currently amended). The method of claim 1 wherein the non-EEG biological metric is heart rate, respiratory rate, or gastrointestinal movement rate.

3 (previously presented). The method of claim 1 wherein the rTMS frequency is equal to, or a harmonic or sub-harmonic of, a non-EEG biological metric that is closest to an intrinsic frequency in a desired EEG band.

4 (currently amended). The method of claim 3 wherein the non-EEG biological metric is heart rate.

5 (previously presented). The method of claim 1 wherein the physiological condition is concentration, sleep, alertness, memory, blood pressure, stress, libido, speech, motor function, physical performance, cognitive function, intelligence, height or weight.

6 (previously presented). The method of claim 1 wherein the neuropsychiatric condition is Autism Spectrum Disorder (ASD), Alzheimer's disease, ADHD, schizophrenia, anxiety, depression, coma, Parkinson's disease, substance abuse, bipolar disorder, a sleep disorder, an eating disorder, tinnitus, traumatic brain injury, post-traumatic stress syndrome, chronic pain, or fibromyalgia.

7 (currently amended). The method of claim 2-3 wherein the intrinsic frequency is in the delta band (<4 Hz), the theta band (4-8 Hz), the alpha band (8-13Hz), the beta band (13-30 Hz), the gamma band (25-100 Hz), or the Mu band (8-13 Hz).

8 (currently amended). A method of improving the symptoms of a person having autism spectrum disorder (ASD) ~~which~~that comprises subjecting the person to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric.

9 (currently amended). The method of claim 8 wherein the non-EEG biological metric is the person's heart rate.

10 (currently amended). A method of improving the symptoms of a person having Alzheimer's disease ~~which~~that comprises subjecting the person to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric.

11 (currently amended). The method of claim 10 wherein the non-EEG biological metric is the person's heart rate.

12 (currently amended). A method of improving the symptoms of a person having chronic pain ~~which~~that comprises subjecting the person to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or a harmonic or sub-harmonic of said non-EEG biological metric.

13 (currently amended). The method of claim 12 wherein the non-EEG biological metric is the person's heart rate.

Remarks

Claims 1-13 were previously pending in the subject application. By this Amendment, claims 2, 4, and 7-13 have been amended. Support for the claim amendments can be found throughout the subject specification and claims as originally filed. No new matter has been added by these amendments. Accordingly, claims 1-13 are presented for consideration by the examiner.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be construed as an indication of the Applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the amendments and remarks set forth herein, is earnestly solicited.

Claims 2, 4, 7-13 have been rejected under 35 U.S.C. §112(b) or 35 U.S.C. §112 (pre-AIA), second paragraph, as being indefinite. The Applicant respectfully traverses this rejection to the extent that it might be applied to the claims now presented for examination.

In order to lend greater clarity to the claimed subject matter, and further to address the issues raised by the Office Action with regard to definiteness of claim language, the Applicant has amended claims 2, 4, and 7-13 herein.

Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §112(b) or 35 U.S.C. §112 (pre-AIA), second paragraph.

Claims 1-13 have been rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-11 of prior U.S. Patent No. 9,308,385 (Our Ref: BTC.103PTX, hereinafter "the '385 patent"). The Applicant respectfully traverses this rejection to the extent that it might be applied to the claims now presented for examination.

For claims 1-7 and 10-13, the Office Action states that the claims are directed to the same methods as those of the '385 patent, only differing in that the language from the "wherein" clause of claims 1, 8, and 10 of the '385 patent has been moved to the preamble in the present corresponding claims. The Applicant respectfully disagrees that a rejection based on statutory double patenting is appropriate with regard to the present application.

A rejection based on statutory double patenting is appropriate only when an application claims identical subject matter to the claims of another application or issued patent. The test for whether an “identical” invention is being claimed is whether the claim in the present application can be infringed without *literally infringing* corresponding claims in the conflicting patent, and vice versa. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) (emphasis added).

The claims of the present application could be infringed without *literally infringing* the claims of the ‘385 patent. For example, the present claims recite methods of “improving a physiological condition or a neuropsychiatric condition,” whereas the ‘385 patent claims a method of “modulating a brain activity” that achieves the result of improvement in a particular physiological condition or a neuropsychiatric condition. Furthermore, the claims of the ‘385 patent recite subjecting the mammal to rTMS “for a time sufficient to modulate said brain activity,” whereas the present claims—which do not recite that the means of improving a physiological condition or a neuropsychiatric condition include modulating brain activity—do not recite such a time limitation.

Where a claim “does not read on an accused product exactly, there can be no literal infringement.” *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1580 (Fed.Cir.1989). Because the claims of the present application do not contain each and every element of the claims of the ‘385 patent, a statutory double patenting rejection is improper.

The Applicant notes that if a double patenting rejection were appropriate at all, the analysis should be based on the doctrine of *non-statutory* double patenting. Non-statutory double patenting prohibits claims in a second patent that are “obvious” variations on claims in an earlier patent, *i.e.*, claims that are not patentably distinct from the earlier claims. *See* MPEP § 804.

There has been no discussion in the Office Action as to why a person of ordinary skill in the art would conclude that the invention defined in the claims of the pending application would have been an obvious variation of the invention defined in the claims of the ‘385 patent. Nonetheless, and not to be construed as agreeing with, or acquiescing to, any rejection based on double patenting, the Applicant is submitting herewith a Terminal Disclaimer solely for the purpose of expediting prosecution of the pending application.

Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §101.

In view of the foregoing remarks and the amendments above, the Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The Applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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